2018 Current Fiscal Year Report: Oncologic Drugs Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018

3. Committee or Subcommittee	3b. GSA Committee No.
Oncologic Drugs Advisory Committee	35

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	09/01/2018	09/01/2020	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	11/28/1990	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports	No Reports for this FiscalYear

17a. Open 2 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 2

Meetings and Dates

Purpose	Start	End
On March 7, 2018, the committee discussed supplemental biologic license application (sBLA) 125557/S013, for BLINCYTO (blinatumomab) injection for intravenous use, application submitted by Amgen, Inc. The proposed indication (use) for this product is for the treatment of minimal residual disease-positive B-cell precursor acute lymphoblastic leukemia. Agency Action: On March 29, 2018, the Agency granted accelerated approval to BLINCYTO (blinatumomab) to treat adults and children with B-cell precursor acute lymphoblastic leukemia (ALL) who are in remission, but still have minimal residual disease (MRD). MRD refers to the presence of cancer cells below a level that can be seen under the microscope.	03/07/2018	03/07/2018

On June 20, 2018, the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee discussed The particular matter for this meeting was to review and discuss a list of molecular targets for which evidence and/or biologic rationale exist to determine their potential relevance to the growth or progression of one or more pediatric cancers and a list of those targets deemed unlikely to be associated with the growth or progression of pediatric tumors for which requirement for early pediatric evaluation would be waived. These lists are expected to fulfill the statutory obligation of the Food and Drug Administration Reauthorization Act (FDARA) and provide some guidance to industry in planning for initial Pediatric Study Plan submissions for new drug and/or biologic products in development for cancer in accordance with the amended provisions of the Pediatric Research Equity Act. The committee also reviewed and discussed considerations other than scientific relevance which the FDA will include in decision making with respect to the need and timing of pediatric evaluation of specific new drug and biologic products. The committee also discussed possible criteria and mechanisms for the prioritization by sponsors and the clinical investigator community of select targeted new agents for pediatric evaluation especially in the setting of multiple same in class agents. Preliminary discussion on approaches to coordination and collaboration for pediatric clinical investigations of new agents that might be pursued to efficiently accommodate international regulatory requirements and global pediatric product development. The OPH sessions were: Topic 1: Target List, Topic 2: FDARA Implementation and Topic 3: Mechanisms to assure efficiency and to enhance global coordination through international collaboration. Agency Action: The Agency is still reviewing recommendations made at this meeting.	06/20/2018 - 06/20/2018

Number of Committee Meetings Listed: 2

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$4,191.00	$26,249.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$155,270.00	$157,666.00
18a(4). Personnel Pmts to Non-Member Consultants	$8,905.00	$17,499.00
18b(1). Travel and Per Diem to Non-Federal Members	$8,964.00	$48,066.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$10,959.00	$16,761.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$42,347.00	$46,547.00
18d. Total	$230,636.00	$312,788.00
19. Federal Staff Support Years (FTE)	1.10	1.10

20a. How does the Committee accomplish its purpose?

The committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and makes appropriate recommendations to the Commissioner of Food and Drugs. The Office of Oncology Drug Products also uses committee members as subject matter experts, on an as needed basis.

20b. How does the Committee balance its membership?

Members are selected from academic and practice settings and include practitioners knowledgeable in the field of general oncology, pediatric oncology, hematological oncology, immunology oncology, biostatistics, and other related professions. The committee includes one technically qualified voting member who is identified with

consumer interests. The Committee may also include one non-voting member who is identified with industry interests.

20c. How frequent and relevant are the Committee Meetings?

The committee met two times in FY-18. On March 7, 2018, the committee discussed supplemental biologic license application (sBLA) 125557/S013, for BLINCYTO (blinatumomab) injection for intravenous use, application submitted by Amgen, Inc. The proposed indication (use) for this product is for the treatment of minimal residual disease-positive B-cell precursor acute lymphoblastic leukemia. Members of the committee agreed that patients with MRD > 0.1% had a very high risk of relapse, but they also noted that the exact population that would benefit from additional therapy is not yet defined. Eight committee members voted “Yes” that the results of MT103-203 demonstrate that for patients with ALL in CR who have MRD > 0.1%, treatment with blinatumomab provides a potential benefit that outweighs the risks from the treatment. Four members voted “No”. It was mentioned that it is not clear where blinatumomab would be used in the treatment cascade given that based on the data presented a “potential” benefit was assumed from trends in the data, but 80% of the patients went to transplantation so the benefit with receiving blinatumomab is confounded. Agency Action: On March 29, 2018, the Agency granted accelerated approval to BLINCYTO (blinatumomab) to treat adults and children with B-cell precursor acute lymphoblastic leukemia (ALL) who are in remission, but still have minimal residual disease (MRD). MRD refers to the presence of cancer cells below a level that can be seen under the microscope. On June 20, 2018, the subcommittee discussed the review and discussion of a list of molecular targets for which evidence and/or biologic rationale exist to determine their potential relevance to the growth or progression of one or more pediatric cancers and a list of those targets deemed unlikely to be associated with the growth or progression of pediatric tumors for which requirement for early pediatric evaluation would be waived. These lists are expected to fulfill the statutory obligation of the Food and Drug Administration Reauthorization Act (FDARA) and provide some guidance to industry in planning for initial Pediatric Study Plan submissions for new drug and/or biologic products in development for cancer in accordance with the amended provisions of the Pediatric Research Equity Act. The committee also reviewed and discussed considerations other than scientific relevance which the FDA will include in decision making with respect to the need and timing of pediatric evaluation of specific new drug and biologic products. The committee also discussed possible criteria and mechanisms for the prioritization by sponsors and the clinical investigator community of select targeted new agents for pediatric evaluation especially in the setting of multiple same in class agents. Preliminary discussion on approaches to coordination and collaboration for pediatric clinical investigations of new agents that might be pursued to efficiently accommodate

international regulatory requirements and global pediatric product development. The OPH sessions were: Topic 1: Target List, Topic 2: FDARA Implementation and Topic 3: Mechanisms to assure efficiency and to enhance global coordination through international collaboration. The subcommittee members commented that the list as currently developed should be as fluid and inclusive as possible. By having a more inclusive list, the subcommittee noted it could serve as a guide for early pediatric drug development. The subcommittee suggested adding RET fusions, RET point mutations, KIT mutations, CCND123, CCNE1, STAG2, and histone1H13D onto the list. The subcommittee discussed how industry sponsors can communicate with FDA and study investigators regarding the level of evidence needed to move an agent forward into early phase clinical trials. Public transparency from the sponsors was encouraged since the FDA is not able to share confidential information. The subcommittee mentioned that they can provide advice and recommendations regarding prioritizing targets on the list and it is recommended that the FDA hold workshops more than twice a year, if necessary, with international involvement. The subcommittee clarified with FDA on how sponsor companies receive guidance for conducting clinical trials from the FDA and EMA, then suggested methods for both organizations to collaborate. Agency Action: The Agency is still reviewing recommendations made at this meeting. It is expected that this committee will meet four to six times in FY-19.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

The committee provides an outside source of scientific expertise in evaluation of clinical trials for oncology drugs. The alternate means of obtaining this advice would be to hire large numbers of scientists on a full time basis at great expense to the government.

20e. Why is it necessary to close and/or partially closed committee meetings?

There were no closed meetings during FY-18.

21. Remarks

No reports are required for this committee.

Designated Federal Officer

Lauren D. Tesh Center for Drug Evaluation & Research, FDA

Committee Members	Start	End	Occupation	Member Designation
Burstein, Harold	07/01/2014	06/30/2018	Associate Professor of Medicine, Dana Farber Cancer Institute	Special Government Employee (SGE) Member

Cristofanilli, Massimo	09/27/2018	06/30/2022	Associate Director of Translational Research and Precision Medicine, Robert H. Lurie Comprehensive Cancer Center	Special Government Employee (SGE) Member
Halabi, Susan	07/01/2017	07/30/2021	Professor of Biostatistics and Bioinformatics, Duke University Medical Center	Special Government Employee (SGE) Member
Hinrichs, Christian	09/27/2018	06/30/2022	Investigator and Lasker Clinical Research Scholar, National Cancer Institute	Regular Government Employee (RGE) Member
Hoffman, Philip	04/25/2017	06/30/2019	Professor of Medicine, The University of Chicago, Section of Hematology/Oncology	Special Government Employee (SGE) Member
Klepin, Heidi	07/01/2016	06/30/2020	Associate Professor of Internal Medicine, Section of Hematology and Oncology, Wake Forest University Health Services	Special Government Employee (SGE) Member
Morrow, Phuong Khanh	03/31/2016	10/31/2019	Executive Medical Director, Amgen Oncology	Representative Member
Nowakowski, Grzegorz	06/04/2015	06/30/2019	Associate Professor of Medicine, Mayo Clinic Rochester	Special Government Employee (SGE) Member
Papadimitrakopoulou, Vassilliki	07/01/2015	06/30/2019	Professor of Medicine, The University of Texas MD Anderson Cancer Center	Special Government Employee (SGE) Member
Pappo, Alberto	06/04/2015	06/30/2019	Member and Head, Division of Solid Malignancies, St Jude's Children's Research Hospital	Special Government Employee (SGE) Member
Preusse, Courtney	06/15/2016	06/30/2019	CONSUMER REPRESENTATIVE, Senior Research Administrator and CLIA Operations Director, Clinical Research Division, Fred Hutchinson Cancer Research Center	Special Government Employee (SGE) Member
Riely, Gregory	07/01/2016	06/30/2020	Associate Attending Physician and Associate Professor, Memorial Sloan-Kettering Cancer Center	Special Government Employee (SGE) Member
Rini, Brian	06/04/2015	06/30/2019	Professor of Medicine, Cleveland Clinic Taussig Cancer Institute, Glickman Urological and Kidney Institute	Special Government Employee (SGE) Member
Roth, Bruce	07/01/2014	06/30/2018	Professor of Medicine, Washington University School of Medicine	Special Government Employee (SGE) Member
Shaw, Alice	07/01/2016	06/30/2020	Director, Center for Thoracic Cancers, Massachusetts General Hospital	Special Government Employee (SGE) Member
Uldrick, Thomas	07/01/2016	06/30/2020	Deputy Head, Global Oncology, Associate Member, Vaccine and Infectious Disease Division, Associate Member, Clinical Research Division Fred Hutchinson Cancer Research Center	Special Government Employee (SGE) Member

Number of Committee Members Listed: 16

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Oncologic Drugs Advisory Committee supports FDA's strategic priorities by reviewing and evaluating available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and makes appropriate recommendations to the Commissioner of Food and Drugs. This supports the development of safe and effective new medical technologies, and advances the status of the Agency as a science-based and science-led regulatory agency, providing global leadership in the protection of public health.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

N/A

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓

Under $100,000 ☐
$100,000 - $500,000 ☐
$500,001 - $1,000,000 ☐
$1,000,001 - $5,000,000 ☐
$5,000,001 - $10,000,000 ☐
Over $10,000,000 ☐
Cost Savings Other ☐

Cost Savings Comments
The utilization of the Oncologic Drugs Advisory Committee enabled the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?
154

Number of Recommendations Comments
The Committee made 154 recommendations from FY-03 through FY-18. See question 20a of the annual report for specific accomplishments.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
80%

% of Recommendations Fully Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
10%

% of Recommendations Partially Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

It usually does. Product approval issues are first released to the sponsor. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐
Issued new regulation	☑
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments

FDA approves or chooses not to approve an investigational new medical product.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

N/A

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	☑
Online Agency Web Site	☑
Online Committee Web Site	☑
Online GSA FACA Web Site	☑
Publications	☑

Other

Access Comments

N/A